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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,790	05/24/2000	Antonio Moroni	498-206	4530

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT PAPER NUMBER

3738

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/577,790

Applicant(s)

MORONI, ANTONIO

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-15 and 17-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's AF submission filed on 3/18/04 has been entered.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6,8-17,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt (5443499) in view of Kuwahara (WO 99/04727). Schmitt discloses a tubular fabric for use as a vascular prosthesis or as an intraluminal prosthesis, col. 2, lines 15-20. Schmitt also discloses a prosthesis that has 115 denier and 100 filaments that are partially oriented to be used for graft material and can be attached with a stent, col. 7, lines 31-44. Schmitt discloses the plurality of polymeric filaments comprise a combination of drawn and partially drawn radial filaments, col. 2, lines 21-28, col. 6, lines 46-58. Schmitt additionally discloses the stent and fabric can be integrated such that controlled radial expansion can be achieved based upon the force exerted, col. 4, lines 65-68 and col. 5, lines 1,2. Schmitt does disclose that polymers, i.e. polypropylenes and copolymers can be used for the filaments, col. 6, lines 21-25.

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However, Schmitt does not disclose the polymeric filaments are made of a naphthalate copolymer. Kuwahara teaches (See US 6346119 for translation) Fig. 2, a stent-graft with a tubular fabric **13** and a deformable stent **14**. Kuwahara et al. teach the graft tube is made of a woven fabric having a plurality of fibers, col. 3, lines 1-3. Kuwahara also teaches the polyester fibers can be made of polyethylene naphthalate (PEN), col. 4, lines 45-49. With respect to claim 8, the prosthesis can have a coating, col. 4, lines 65-67. The examiner asserts that the claimed physical properties and formula (in this case, the material being radiation resistant and hydrolytically stable) are present in the Kuwahara material to some extent even though they are not explicitly recited. All materials can be considered radiation resistant, since they are inherently exposed to some sort of radiation, such as radio waves, visible radiation from lights, etc. or possibly UV radiation. Since there is no objective or quantitative measurements as to ascertain what is considered "radiation resistant" or "hydrolytically stable" the properties are inherently possessed by the prior art material. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art. The fabric is inherently stable at least *about* 120°C because this temperature is well below the melting point of PEN, which is 270°C. It would have been obvious to one of ordinary skill in the art to use naphthalene dicarboxylate derived polymeric filaments as taught by Kuwahara in the Schmitt prosthesis to provide a more stable implant.

Claims 18,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt '499 in view of Kuwahara (WO 99/04727) and Vanney et al. (5876436). Schmitt and Kuwahara are explained supra. Schmitt does disclose drawing yarns to a point

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prior to the fracture point to increase the tensile strength and decrease the elongation to failure, col. 4, lines 14-16. However, Schmitt and Kuwahara do not disclose a method of producing the prosthesis under steam sterilization. Vanney et al. teach that a fabric prosthesis is steam sterilized, col. 8, lines 1-7. It would have been obvious to one of ordinary skill in the art to use steam sterilization on a fabric prosthesis as taught by Vanney et al. and to incorporate naphthalene derivative filaments as taught by Kuwahara for the prosthesis of Schmitt in order to provide a safe, stronger and sterile implant for the patient. It is well known in the surgical art that prostheses should be sterile for implantation in order to reduce any risk of bacterial infection.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt '499 in view of Kuwahara (WO 99/04727) and Schmitt et al. (5697970). Schmitt and Kuwahara are explained supra. However, Schmitt and Kuwahara do not disclose the prosthesis comprising a series of crimps. Schmitt et al. '970 teach (Figs. 1,2) that crimps are applied to graft prostheses for enhancing pliability, ease of handling and structural stability, col. 3, lines 14-43. It would have been obvious to one of ordinary skill in the art to incorporate naphthalene dicarboxylate derived polymeric filaments as taught by Kuwahara and use crimps as taught by Schmitt '970 with the prosthesis of Schmitt '499 such that it is more flexible and improve the chemical stability of the implant.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1,11,17,18 have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments with

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respect to the Schmitt '499 reference have been fully considered but they are not persuasive. In col. 6, lines 46-59, Schmitt discloses the manufacture of a prosthesis with both drawn and partially drawn filaments, nowhere does it state that the prosthesis is implanted to achieve drawing of the filaments. Additionally, whether or not the prosthesis is implanted to achieve drawing of filaments is irrelevant because the features upon which applicant relies (i.e., drawn prior to formation) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

TC 3700, AU 3738  
Brian E. Pellegrino

